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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board to the National Center for Toxicological Research (NCTR).

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 26, 1999, 12 noon to 5:30 p.m., and April 27, 1999, 8:30 a.m. to 1 p.m.

Location: NCTR, Bldg. #12, Conference Center, Jefferson, AR.

Contact Person: Ronald F. Coene, NCTR (HFT-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12559. Please call the Information Line for up-to-date information on this meeting.

Agenda: The board will be presented with draft reports on evaluations of three of NCTR's programs in Biochemical Toxicology, Genetic Toxicology, and Molecular Epidemiology, for their review, discussion, and approval. The draft reports are the products of three site visit teams who conducted on-site reviews over the last year. The staff from these programs will provide a preliminary response to the issues raised and recommendations made. Two progress reports will

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be presented to the board on the recommendations it made at its last meeting on NCTR's Neurotoxicology Program and Biometry and Risk Assessment Program. The NCTR Director will also provide a center update.

Procedure: On April 26, 1999, from 12 noon to 5:30 p.m., and April 27, 1999, from 8:30 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the board. Written submissions may be made to the contact person by April 15, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on April 27, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On April 27, 1999, from 12 noon to 1 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

The Commissioner approves the scheduling of meetings at locations outside the Washington, DC area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: April 1, 1999

Michael A. Friedman
Deputy Commissioner for
Operations

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